

# **Mammography Quality Standards Act (MQSA)**

## **Enhancing Quality Using the Inspection Program (EQUIP)**

### **Frequently Asked Questions - Facilities**

The purpose of this document is answer questions facilities may have about the EQUIP inspection questions. The three questions, and their sub-questions, that the inspector will be answering during the annual inspection, as well as the compliance pathway, are outlined below and followed by FAQs. More information about the EQUIP initiative may be found in the [MQSA Insights article](#), and the “Important Information about the EQUIP Initiative” that inspectors will provide to facilities at their MQSA inspections.

#### ***Quality Assurance — Clinical Image Corrective Action***

##### ***1. Does the facility have procedures for corrective action (CA) when clinical images are of poor quality?***

*(a) Do the procedures include a mechanism for providing ongoing IP feedback on image quality to RT's or other designated facility personnel?*

*(b) Do the procedures require documenting any corrective actions taken and documenting the effectiveness of any corrective actions taken?*

##### **Q1. Does the facility's system for corrective action when clinical images are of poor quality need to be in the form of a written SOP?**

No. Facilities are not required to create a written procedure. A facility may verbally explain its system to the inspector. Whether written or verbal, the system must include mechanisms for ongoing IP feedback and for documenting and assessing corrective actions. The details of those mechanisms will not be assessed by the inspector. He/she will assess that a system is in place and contains those two elements.

##### **Q2. Who determines whether images are of poor quality?**

For the purpose of this inspection question, the IP is responsible for determining if images are of poor quality and providing feedback.

##### **Q3. Does the FDA have examples of acceptable mechanisms for the IP to provide feedback on poor image quality?**

No. The mechanism for the IP to provide feedback on poor image quality is left up to the facility.

**Q4. How should a facility document any corrective actions taken or the effectiveness of any corrective action taken?**

It is up to the facility to determine how to document any corrective action taken or the effectiveness of any corrective actions taken.

**Q5. If there were no images of poor quality, does there have to be any documentation of the fact that there was no corrective action?**

No.

**Q6. Is there a specific way a facility should determine the effectiveness of corrective actions?**

No. It is up to the facility how it determines the effectiveness of any C/A taken.

**Q7. Is there a timeframe for corrective action to be taken when the IP determines images are poor quality?**

No. The facility determines its timeframe for completing any needed corrective action.

**Q8. Is there a requirement for how long a facility should retain feedback from the IP to personnel when there are images of poor quality?**

No. There is no requirement on how long the facility should retain clinical image quality feedback from the IP.

**Q9. If a facility is cited under this question and a written response is required, can the facility respond with a written explanation of how it has set up its system rather than submit a written procedure?**

Yes.

### ***Clinical Image Quality***

**2. Does the facility have procedures to ensure that clinical images continue to comply with the clinical image quality standards established by the facility's accreditation body?**

*(a) Do the procedures include a mechanism for regular reviews of image quality attributes of a sample of mammograms performed by each active RT and a sample of mammograms accepted for interpretation by each active IP?*

*(b) Is there documentation of such review since the last inspection?*

**Q1. Is a regular review required and how often?**

Yes. Since the reviews are discussed at the time of the inspection and need to have been done since the last inspection, by default the review needs to be done at least annually. More frequent review (i.e., monthly, quarterly) is encouraged.

**Q2. Is written documentation of the review required?**

Yes. A verbal demonstration or discussion will not be accepted. Documentation can include such things as a summary report, signed statement by LIP that a review was performed, clinical image review meeting records, memos of review results to RTs and IPs, etc.

**Q3. Does repeat analysis QC count as a review?**

No. Repeat/reject rates are not necessarily directly linked to poor quality images presented for interpretation to the IP.

**Q4. Does the review have to be performed by the Accreditation contact?**

No. It is the responsibility of the facility to ensure the review is performed. Anyone may gather and compile data in order to report on the clinical image quality for the facility.

**Q6. Does the review need to be signed?**

No.

**Q7. Does the review need to be dated?**

Yes.

**Q8. Does daily review of every mammogram at the time of interpretation count as “regular review of a sample of images”?**

No.

**Q9. Is there a requirement of an acceptable sample size of images to review for each active RT and IP?**

No. The sample size of images to review is left up to the facility to determine.

**Q10. Are there any exceptions for facilities with a large number of RTs and IPs?**

No. The review must include all RT's and IP's.

**Q11. Do employees who have left the facility have to be included in the review?**

No. Only employees that are actively performing/interpreting mammograms at the time of the review need to be included in the review.

**Q12. If there is only one IP in facility, is someone else responsible for reviewing him or her?**

No. The sole IP at the facility would also be the LIP and would need to assess his/her own images for quality.

**Q13. What are the AB standards for image quality attributes?**

There are eight image quality attributes listed in 900.4(c)(2)(i-viii). They are: positioning, compression, exposure level, contrast, sharpness, noise, artifacts, and examination identification.

**Q14. For the 3D portion of DBT units are there any FDA clinical image quality standards?**

Yes. Clinical image quality is not specific to any particular technology. The image quality attributes can be used to evaluate images of all 3 mammographic modalities (DBT, FFDM, and screen/film).

**Q15. Does the system to ensure that clinical images continue to comply with clinical image quality standards established by a facility's accreditation body have to include a written SOP?**

No.

### ***Quality Control***

**3. Does the facility have a procedure for LIP oversight of QA/QC records and corrective actions?**

*(a) Does the procedure include requirements for LIP oversight of QA/QC records, including review of the frequency of performance of all required tests?*

*(b) Does the procedure include requirements for LIP review to determine whether appropriate corrective actions were performed when needed?*

**Q1. Does the system for LIP oversight have to be a written SOP?**

No. The LIP may provide an attestation or can verbally answer questions regarding oversight of QA/QC records.

**Q2. If the LIP is located off site, can he or she be contacted via phone on the day of the inspection to discuss the oversight of QA/QC records?**

Yes.

**Q3. What documentation is needed to effectively demonstrate a system is in place for LIP oversight of QA/QC records and corrective actions?**

The facility may provide LIP attestation or the LIP may verbally answer questions regarding C/A during the inspection, or an SOP signed by the LIP may be presented to the inspector.

**Q4. Can the facility designate another individual to perform the oversight LIP responsibilities of the QA/QC records?**

Yes. The LIP may designate someone other than the LIP to perform the oversight, but the LIP is the one responsible and will be the one attesting, in writing or verbally, or signing an SOP.

**Q5. If the LIP is offsite or part of a tele-radiology company, is oversight of QA/QC part of his or her responsibility?**

Yes. If that person is designated as the LIP for MQSA purposes, then he/she must comply with the MQSA regulations which state that oversight of QA/QC records and corrective actions are the LIP's responsibility.

**Q6. Is there a required frequency for "LIP review" of QA/QC records?**

No. The LIP review should be appropriate to ensure the QC tests are performed at the required frequency and any needed C/A is taken.

**Q7. Do LIPs need training in QA/QC?**

No.

**Q8. If there were no actionable QA/QC test results, does there have to be any documentation of the fact that no C/A was performed?**

No. The facility still needs to provide the LIP attestation or an SOP signed by the LIP, or the LIP may verbally answer questions regarding C/A during the inspection.

***Compliance Pathway***

- *During the initial year of implementation facilities will not be cited for violations of the Clinical Image Quality Review (CIQR) requirements*
- *MQSA Inspection Year Two: Facilities will receive Level 2 citations for deficiencies noted by MQSA inspectors in the area of CIQRs. The facility will be required to provide a written response to the FDA district office within 30 days*
- *MQSA Inspection Year Three: A repeat violation of the CIQRs will be cited as a Level 2 repeat violation. The facility will be required to provide a written response to the FDA district office within 15 days and will be referred to its accreditation body for an evaluation of clinical images.*

**Q1. Will facilities be cited for any noncompliances related to clinical image quality in year one?**

No. Citations related to clinical image quality will not be issued during the first year. The first year of the EQUIP initiative allows the facility to become familiar with the requirements.

**Q2. What are the reasons for the EQUIP initiative?**

The EQUIP initiative places emphasis on the significance of clinical image quality, one of the most important determinants of the accuracy of mammography. It also highlights the LIP's responsibilities for image quality.

**Q3. Do you have any sample clinical image quality programs or procedures that will be acceptable to FDA?**

No. Each facility is responsible for implementing a program that is appropriate for its site.

**Q4. How soon after the first year must documentation of a review being performed be provided to the inspector?**

At least one review needs to be completed by the annual inspection that follows the inspection where EQUIP is introduced.

**Q5. If during the first year, a facility's system/procedure was deemed inadequate and this continues into the second year, will the initial citation be treated as a repeat?**

No. Citations related to clinical image quality will not be issued during the first year. The first year of the EQUIP initiative allows the facility to become familiar with the requirements. If a facility is issued a citation in year two, and the same noncompliance is found in year three, then the citation will be treated as a repeat. Please see compliance pathway above.

**Q6. When will the educational or first introduction year of EQUIP begin?**

The effective date of the educational year will begin January 1, 2017.

**Q7. Who should a facility contact if it needs further clarification about the new inspection questions?**

A facility should contact its inspector first with questions related to the clinical image quality requirements. Inspector contact information can be found on the "MQSA Inspection Confirmation". Facilities may also contact the MQSA Facility Hotline at 800-838-7715 or by e-mail at [MQSAhotline@versatechinc.com](mailto:MQSAhotline@versatechinc.com).